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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/970,643 | 10/05/2001 | Wendy J. Davis-Hoover | | 2230 |

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EXAMINER

AFREMOVA, VERA

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1651

DATE MAILED: 11/19/2002

2

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/970,643

Applicant(s)

Davis-Hoover et al.

Examiner

Vera Afremova

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Oct 5, 2001
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

Art Unit: 1651

DETAILED ACTION

Claims 1-6 are pending and under examination.

Specification

The disclosure is objected to because of the following informalities: some information related to the deposit of microorganism *Pseudomonas aeruginosa* strain CHL004 or strain ATCC 55937 is missing. The current address of International Depository, which is ATCC, the date of deposit in ATCC and the clear relationship between various designation numbers of the applicants' strain CHL004 and ATCC 55937 should be within the text of the specification. Appropriate correction is required.

Claim Objections

Claims 1-6 are objected to because of the following informalities: the Latin name of microorganism *Pseudomonas aeruginosa* contains a typing error. The Latin name of microorganism should be italicized. Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 112

Deposit

Claims 1-6 are rejected under 35 U.S.C. 112, *first paragraph*, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Art Unit: 1651

The claims require one of ordinary skill in the art to have access to a specific microorganism *Pseudomonas aeruginosa* CHL004. Because the microorganism is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the microorganism is not so obtainable or available, the requirements of 35 U.S.C. 112 may be satisfied by deposit of the microorganism. The specification does not disclose a repeatable process to obtain the microorganism and it is not clear from the specification or record that the microorganism is readily available to the public.

The objection and accompanying rejection may be overcome by establishing that each microorganism identified is readily available to the public and will continue to be so for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer, or by an acceptable deposit as set forth herein. See 37 CFR 1.801-1.809.

If the deposit is made under the terms of the Budapest Treaty in the International Depository such as ATCC, for example, then an affidavit or declaration by applicants or a statement by an attorney of record over his/her signature and registration number, stating that the deposit has been made under the Budapest Treaty and that all restrictions imposed by the depositor on availability to the public of the deposited material will be irrevocably removed upon issuance of the patent would satisfy the deposit requirement. See 37 CFR 1.808.

Art Unit: 1651

Claims 1-6 are rejected under 35 U.S.C. 112, *second paragraph*, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 4 are rendered indefinite by the designation number of the claimed strain such as "CHL004". The sole designation of microbial strain by the internal designation creates ambiguity in the claims. For example, the strain disclosed in this application could be designated by some other arbitrary means, or the assignment of the strain name could be arbitrary changed to designate other strain. If either event occurs, one's ability to determine the metes and bounds of the claims would be impaired. See *In re Hammack*, 427 F.2d 1378, 1382; 166 USPQ 204,208 (CCPA 1070). Amendment of the claims to refer to the deposit accession number of the claimed strains in IDA such as ATCC, for example, would obviate this rejection.

Claims 1 and 4 are rendered indefinite by the phrase "growing" because the claims are directed to a product comprising a microorganism not to a method of growing or culturing a microorganism. It is uncertain as claimed whether "growing" means "viable" for the claimed product as intended. It is uncertain as claimed whether "growing on solid support" is intended as an inherent identifying characteristic the strain CHL004 which is capable of growing on a solid support.

Claim 1 is indefinite with regard to limitation drawn to "an environment" because the claim is directed to a product not to a method of using a product in "an environment". It is uncertain what components derived from "environment" are intended to be within the claimed

Art Unit: 1651

product. Are lead and phosphate included in the claimed product? Is the claimed stain CHL004 capable to utilize lead and phosphate? Is the claimed stain CHL004 capable to utilize lead and phosphate only under condition of stoichiometric equivalent amount of phosphate to lead?

Claims 2 and 3 recite the limitation "the support" in the claimed product. There is insufficient antecedent basis for this limitation in the claim 1.

Claim 4 is rendered indefinite by the phrase "also" or "also contains". It is uncertain what would be "also" besides iron and the strain CHL004 in "said matrix".

Claims 5 and 6 recite the limitations "an environment containing arsenic" and "an environment containing arsenic". There is insufficient antecedent basis for these limitations in the claim 4. Is "a solid support" of claim 4 intended as "an environment"? Claims 5 and 6 are directed to a product not to a method of using a product in an "environment". It is uncertain what components derived from "environment" are intended to be within the product of claims 5 and 6. Are arsenic and/or cadmium included in the claimed product? Is the claimed strain CHL004 capable to utilize arsenic and/or cadmium?

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Vesper et al. [U].

Art Unit: 1651

The claim is directed to a product comprising viable *Pseudomonas aeruginosa* strain CHL004 on a solid matrix.

Vesper et al. [U] disclose a product comprising viable *Pseudomonas aeruginosa* strain CHL004 on a solid matrix such as solid culture medium or filter paper (page 208, last 2 lines). The cited reference teaches that strain *Pseudomonas aeruginosa* CHL004 is capable to remove heavy metal such as lead from solid media and soil (abstract).

The cited reference is considered to anticipate the claimed invention because it discloses a product comprising identical components as the claimed product such as identical solid matrix and identical microbial strain which inherently possesses all characteristics of the strain CHL004 including capability to utilize phosphate and/or heavy metals including lead under specific conditions as intended.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vesper et al.

[U] taken with US 4,728,427 [A] and US 5,863,750 [B].

Art Unit: 1651

Claims are directed to a product comprising viable *Pseudomonas aeruginosa* strain CHL004 on a solid matrix. Some claims are/are further drawn to the use of a solid matrix containing synthetic polymer or activated carbon or iron. The intended use of the claimed product is removal of metals such as lead, arsenic and/or cadmium from an environment.

Vesper et al. [U] is relied upon as explained above for the disclosure of a product comprising viable *Pseudomonas aeruginosa* strain CHL004 on a solid matrix such as solidified medium or filters. The cited reference teaches the use of the stain CHL004 for removal of lead from an environment or from soil contaminated with heavy metals including lead. The cited reference is lacking disclosure related to the use of some particular solid matrix materials such as synthetic polymer, activated carbon or iron.

However, US 4,728,427 [A] teaches that the microbial products comprising various representatives of *Pseudomonas species* (col. 4, line 26), which are capable to reduce amounts of heavy metals including metals such as cadmium, lead and/or arsenic (col. 2, line 38; col. 3, line 25 and line 36) in contaminated environments, are immobilized on solid matrix materials including plastic or synthetic polymer (col.5, lines 9-10). The immobilized microbial preparations allow for a continuous process of decontamination with periodic withdrawals and separations of microbial cells and metals from environment (col. 5, lines 5-15). The cited patent also teaches that the products with microbial cells could incorporate nutrients including phosphates (col. 3, lines 25) in order to meet the nutrient requirements of the immobilized microbial preparations (col. 5 , lines 17).

Art Unit: 1651

US 5,863,750 [B] teaches the use of various solid support materials for immobilization of microbial cells intended for detoxification of contaminated environments. These support materials include activated carbon and/or iron which facilitates the recovery of microbial products due to magnetic ability (col. 33, lines 26-31).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to use various solid matrix/support materials in the microbial preparations intended for environmental decontamination comprising various microbial stains including strains belonging to *Pseudomonas sp.* or strain CHL004 with a reasonable expectation in success for obtaining products effective in environmental decontamination including removal or reduction of heavy metals because these solid matrix/support materials have been known and used as adequately demonstrated by the cited prior art. One of skill in the art would have been motivated to use microbial stains including stain CHL004 in a form comprising solid matrix/support for the expected benefit of immobilized microbial preparations in a continuous process of decontaminating the heavy metal containing environments which allows to maximize microbial removal of heavy metals and to facilitate withdrawal or separation of microbial cells and metals from the environment under treatment. Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary. It would be within the purview of one having ordinary skill in the art to adjust stoichiometric equivalents of chemical elements or ions involved in a particular chemical reaction or process of choice as intended.

Art Unit: 1651

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (703) 308-9351. The examiner can normally be reached on Monday to Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vera Afremova

Art Unit 1651

November 15, 2002.



VERA AFREMOVA

PATENT EXAMINER